

1 UNITED STATES DISTRICT COURT
2 NORTHERN DISTRICT OF WEST VIRGINIA

3 Biogen International GMBH
4 and Biogen MA, Inc.,

5 Plaintiffs,

6 vs. CIVIL ACTION NO.

7 1:17-cv-116

8 Mylan Pharmaceuticals,
9 Inc.,
10 Defendant.

11 - - -

12 **TRANSCRIPT**

13 of proceedings had in the telephonic status conference of
14 the above-styled action on February 5, 2020, before Honorable
15 Irene M. Keeley, District Judge, at Clarksburg, West Virginia.

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Wednesday Afternoon Session,

February 5, 2020, 4:30 p.m.

— — —

THE COURT: Hello. This is Judge Keeley. Do I have the parties on the line?

MR. MONROE: Yes, Your Honor.

THE COURT: All right. Thank you. I'm conducting this from the courtroom because I just finished a sentencing. If you have any trouble understanding me or hearing me, please let me know, because I'm speaking into a microphone rather than directly into the phone.

All right. So this is Biogen versus Mylan, and we're here for the purpose of receiving an update from the parties following their receipt of the decision at the PTAB today of Mylan's IPR. Who wishes to speak? Note your appearance as you address me, please, so the record will be clear.

MR. COPLAND: Your Honor, this is Gordon Copland for Mylan. Also on the line are Shannon Bloodworth and Dave Anstaett. I think Shannon Bloodworth will give you a short update on where the parties are in discussions in light of the PTAB decision.

THE COURT: Okay. Ms. Bloodworth, I'm happy to hear from you.

MS. BLOODWORTH: Thank you, Your Honor.

The PTAB did issue its decision, as Your Honor is aware,

1 and that decision did not go in Mylan's favor. Mylan is still
2 considering that decision, obviously, in its future courses,
3 but for the purposes of this trial, the Court will no longer
4 need to reach the issue of 103, and that obviously has a very
5 slimming effect to this trial because we will now have several
6 less witnesses, so I think I would say the trial days will
7 require probably in the range of two instead of the seven that
8 we were currently planning on.

9 The logistics changes a little bit. Mylan's case in chief
10 now becomes the 112 case, and with that we will be calling a
11 couple of the witnesses on our "may call" list, particularly
12 Dr. Katherine Dawson and Dr. O'Neill. We reached out to Biogen
13 to let them know that was our intention. We have not heard if
14 they will be bringing them to trial at that request. And so --
15 and we also have some dep designations that will now form the
16 basis for Dr. Greenberg's 112 testimony.

17 So what we had proposed was that we would -- I think in
18 all -- I think to make this very efficient and try to have an
19 orderly presentation of evidence, we would resume court on
20 Friday morning and play those dep designations that we were
21 going to take out of order in an awkward way when we were
22 having Dr. Greenberg appear all at once because we were trying
23 to call witnesses at one time, and then obviously I think
24 Biogen will have Dr. Wynn in rebuttal. And so depending upon
25 the adverse witnesses that we would now like to call and

1 whether or not they're coming to trial, again, is a much more
2 efficient case at this point, and we just think taking until
3 Friday morning to figure out all these issues is a more
4 efficient way to proceed.

5 THE COURT: You're suggesting that we not have trial
6 tomorrow.

7 MS. BLOODWORTH: Yes, Your Honor. I think we will have --
8 if Your Honor does want to have some testimony tomorrow, I
9 think we will have Dr. Lukashev designations.

10 MR. MONROE: Your Honor, this is James Monroe on behalf of
11 Biogen, if I may just comment briefly. We did respond --

12 THE COURT: Excuse me. May I just inquire of
13 Ms. Bloodworth if she's finished. I think we should allow her
14 to conclude her remarks before I hear from you. I understand
15 you're anxious to chime in on this, but Ms. Bloodworth, have
16 you finished?

17 MS. BLOODWORTH: Yes, Your Honor. I think I was just
18 saying, again, I was trying to stretch efficiency but also
19 trying to -- we -- I think the real outstanding question is
20 whether or not Biogen will allow us to call those adverse
21 witnesses live, and then again the dep designations, which,
22 again, we can now orderly present the evidence on the 112 case
23 by having them played.

24 THE COURT: Okay. So I understand the 103 issues of
25 obviousness have been decided, and they've been decided in

1 Biogen's favor, and the 112 issues remain in the case. So that
2 burden of going forward remains on Mylan, correct, their
3 defenses?

4 MS. BLOODWORTH: Yes, Your Honor. We will still be in our
5 case in chief on 112 issues.

6 THE COURT: Okay. Thank you.

7 Now I'm happy to hear from Biogen.

8 MR. MONROE: I apologize, Your Honor. I did not intend to
9 interrupt Ms. Bloodworth.

10 We have responded to the inquiry. We sent a response
11 around 3:30. We noted that we agreed that Mylan was estopped
12 from moving forward on the 103 case and could only proceed on
13 112. We did ask if they would agree to have a stipulation to
14 that. Our client would like to ensure that there's a written
15 record that there's a stipulation to estoppel that's by
16 statute, and we also had asked if they would agree to strike
17 the testimony -- in that stipulation, agree to striking the
18 testimony of Dr. Greenberg that was presented on Tuesday other
19 than his qualifications, Your Honor, given that all of that
20 testimony was directed to the 103 issues.

21 We also noted that we disagreed with the need to recess
22 until Friday. Dr. Greenberg was in the middle of his direct,
23 and he was about two-thirds of the way through and very close
24 to the 112 issues, and if this decision had not come down, he
25 would have continued to testify in due course and gone through

1 completely and all of his 112 arguments, and therefore we don't
2 think there's a reason to read more witnesses now and start
3 playing deposition designations when he's already been in the
4 course of his testimony. We do agree he should take up his
5 testimony at that point in the slide set which was about the
6 112 issues.

7 And so we propose that for efficiency, to ensure we're
8 continuing on track, is that we would continue tomorrow morning
9 as planned, with him continuing, but only on 112, and then we
10 would agree to call -- we could start our case in chief, our
11 case in rebuttal, or -- and call Dr. Wynn.

12 And we had proposed -- we don't disagree with the concept
13 that they'd like to go ahead and do their deposition
14 designations, but we thought it might make sense, for the
15 reasons that Ms. Bloodworth noted, to give the parties a little
16 more time so Mylan can narrow its deposition designations so
17 they're limited to the 112 issues, and then we can -- we can
18 confer tomorrow about those issues so that on Friday those
19 deposition designations could be played following the hearing
20 from Dr. Wynn on the 112 issues.

21 With respect to the witness issues, we also noted that in
22 view of the decision that now removes the 103 issues from this
23 case that we would not be calling live Dr. O'Neill, Dr. Dawson,
24 Dr. Thisted, Dr. Duddy, Dr. Brundage, or Mr. Jarosz. None of
25 those witnesses are now necessary in view of the IPR decision,

1 and we don't believe any of their testimony has any relevance
2 to the 112 issues.

3 To the extent that Mylan is noting that it wants to call
4 Dr. O'Neill and Dr. Dawson, there was a provision set forth in
5 the pretrial order that if they wanted to call them as part of
6 their case in chief, that they could do so by designations, if
7 we did not call them, and that was specifically in case of a
8 situation like this. And so we are now not calling any of
9 those witnesses and instead limiting our presentation in our
10 rebuttal case to the narrow issue of 35 U.S.C. 112.

11 So we think it makes sense to just proceed as originally
12 planned, with Dr. Greenberg finishing his testimony, and then
13 we will have Dr. Wynn and then we'll go over till Friday and
14 have deposition designations, and then if Your Honor wants
15 closings, then that also.

16 So that would be our response to Mylan. And I know we
17 responded at 3:30 to their email about 2:45, so they may not
18 have had a chance to digest all of that yet, but that's what
19 Biogen would propose to just keep the case moving.

20 THE COURT: Ms. Bloodworth, do you wish to be heard again?

21 MS. BLOODWORTH: Yes, Your Honor. And I think my specific
22 request and question was whether or not, if they're not
23 intending to call Dr. O'Neill or Dr. Dawson, but whether or not
24 they will bring them to trial live, because as Your Honor
25 heard, if they do not, we have to do the dep designations and

1 exchange it with plaintiff and get those ready to play.

2 And limiting a case takes a lot of work, and I don't think
3 it's -- this is our case in chief, and we don't want to present
4 our evidence in our case in chief in the manner in which
5 Mr. Monroe wants us to. You know, this testimony does -- it
6 was -- like I said before, even when we were going to do it on
7 Wednesday, it was awkward, and Your Honor can see the slides we
8 had. We were going to try and call out potential testimony
9 from witnesses for Dr. Greenberg to be able to put in his
10 opinions.

11 Now we are, as Mr. Monroe acknowledged, dropping several
12 witnesses. We have the -- we have to take a day to properly
13 order the presentation of the evidence, and we think it's
14 efficient and also the order in which Mylan would prefer to put
15 in its case in chief in to the Court.

16 And a half day adjournment I understand is a request, or a
17 full day is a request, but again, the parties were anticipating
18 a seven-day trial, and we certainly slimmed it down quite
19 substantially.

20 THE COURT: Are either Dawson or O'Neill, or both of them,
21 still employed by Biogen?

22 MR. MONROE: Dr. O'Neill has not been employed by Biogen
23 for a while and is not under its control. Dr. Dawson is
24 employed by Biogen and given the testimony is about the 103
25 issues, we're not calling her as a witness and don't believe

1 she should be called live to come here to testify to what
2 issues which we were intending to raise, Your Honor, during
3 this call.

4 We were also going to propose that we would like to file a
5 motion in limine with respect to them raising the items that
6 were in -- the topics on the 112 issue that were in the opening
7 slides on that issue. As I noted during my opening, Your
8 Honor, those issues are -- those facts are irrelevant to what
9 the patent teaches to the skilled artisan; and secondly, they
10 did not have that type of data or that type of information as a
11 basis prior to their opening slide.

12 THE COURT: Okay. Just a minute. I'm not expanding this
13 discussion to the motion in limine on who's going to testify
14 about what. That's not happening right now. And I will tell
15 you again, as I did yesterday, as a trial judge, I'm looking
16 for live testimony where I can get it. So if Dr. Dawson was
17 planning to be here anyway and now you've just decided as a
18 matter of strategy not to bring her in, it will be helpful to
19 me in making the decision on your argument to have seen the
20 witness live.

21 If you choose not to bring her in, I'll certainly include
22 that in the calculation of my weight, the weight that I give to
23 her testimony and your rebuttal, and also any motion in limine
24 that you might be filing.

25 I gather that Dr. O'Neill is not under your control and on

1 that, Ms. Bloodworth, I think you're at a stalemate on that
2 one. How can I order Biogen to bring in someone who's not an
3 employee and who is not controlled by Biogen at this time?

4 MS. BLOODWORTH: I'm not asking for that. I'm simply
5 asking for Biogen, if they would voluntarily bring Dr. O'Neill
6 to trial. If they are not, which I hear they are not intending
7 to call him any longer, then we will designate Dr. O'Neill's
8 deposition testimony in light of him appearing live, and we
9 need to start that process because we don't have that dep
10 designation done yet because he was going to be appearing live.

11 THE COURT: Certainly. And I would just remind, again,
12 both sides, the trial judge really likes to see and hear live
13 testimony. It's much more compelling. And I would certainly
14 support any attempt by Biogen to get Dr. Dawson in here. I've
15 read through the excerpts of her deposition that were used
16 previously in the motions, and there's a lot lost on the page
17 that I'd like to see in person.

18 What's Biogen going to do about that?

19 MR. MONROE: Well, I was going to inquire as to her
20 availability, Your Honor. We had indicated that she would be
21 called as a witness depending on the outcome of the IPR,
22 because they're issues related to the 103 issues.

23 THE COURT: When were you planning to call her had you
24 lost on the IPR? Let's go at it that way.

25 MR. MONROE: She wasn't going to be until probably next

1 week.

2 THE COURT: Well, I've got the whole week reserved for you
3 next week, and this is a trial to the Court, so if you all want
4 to interrupt the trial and come back for that purpose next
5 week, I'm here.

6 MR. MONROE: Your Honor, we will check on her availability
7 and obviously, with our client, on that issue. The Dr. O'Neill
8 issue, I know we're unable to bring him.

9 THE COURT: But you were going to bring him had the IPR
10 not gone your way.

11 MR. MONROE: We had asked about his availability and were
12 hoping for him to be here this week.

13 THE COURT: Okay.

14 MR. MONROE: But we predicated that on the obviousness.

15 THE COURT: All I'm going to suggest is -- this is
16 probably directed more to Biogen than it is to Mylan at this
17 point. Just remember I'm the finder of fact. I make the
18 decision in this case. And to the extent that the testimony
19 comes in live and it comes in efficiently and it comes in in an
20 economically advantageous way to everybody's time, that's
21 certainly something that I view as worthwhile goals in a
22 litigation. If it can't happen that way because Dr. Dawson is
23 not available till next week, then we'll recess and we'll come
24 back when she is available.

25 Since you all are from out of town and one never knows what

1 the weather is going to be in West Virginia in February, I
2 think the sooner you can get her in, the better for all of us.

3 And with regard -- moving on then to the Greenberg issue,
4 what, Ms. Bloodworth, is the reason you would like to delay him
5 and not put him on tomorrow?

6 MS. BLOODWORTH: Your Honor, first, that I'd like to play
7 Dr. Lukashev's deposition live in the courtroom because he --
8 it is a very critical piece of our 112. He is the named
9 inventor on the patent.

10 The second is I'm going to be devoting a lot of my energy
11 to slimming down this case, and it is, as you know, a large
12 amount of decisions and issues that need to go on. And this
13 has been a very difficult day for Mylan, and I don't want --
14 that's not on the Court. It's on us. But having a half a day
15 where we can reach -- makes us more efficient in putting
16 Mylan's case in chief on in 112 would be, I think, very
17 beneficial. And we would start with Lukashev's dep
18 designations Thursday afternoon and I think we will have
19 witnesses completed, all of the witnesses, even if Biogen
20 brings both O'Neill and Dr. Dawson, finished by Tuesday.

21 THE COURT: So what would we be doing tomorrow morning?

22 MS. BLOODWORTH: Tomorrow morning, Your Honor, the parties
23 would be meeting and conferring and working to define the
24 evidence for the 112 case and prepare it.

25 THE COURT: And where would you be doing that?

1 MS. BLOODWORTH: We'll be doing it by phone. I'm
2 currently at the Holiday Inn -- Hilton Garden Inn in
3 Clarksburg, but we'll be doing it by phone. We exchanged dep
4 designations. We have it set out where we bring counters, they
5 counter, and we can work out objections, and then we have to
6 make the reports and the videos.

7 And then once we understand what that evidence will look
8 like that will be in, depending on the evidence, I will then
9 understand the definitive scope of Dr. Greenberg's 112
10 testimony.

11 THE COURT: All right. Hold on a second. Could both
12 parties hold on for just a moment.

13 MS. BLOODWORTH: Of course.

14 (Discussion held off the record.)

15 THE COURT: All right. I just spoke with the clerk in
16 order to determine space availability here at the main
17 courthouse tomorrow. I foresee, just based on the way things
18 have worked out in this case before today, that if I don't
19 bring you all in to the courthouse to have you work these
20 issues out tomorrow morning, we'll never get to testimony
21 tomorrow afternoon and we'll spend a lot of the time on what
22 would be possibly needless motion practice. If you're here in
23 the courthouse in conference rooms, walking down the hall,
24 talking to each other, and I'm across the hall in my chambers,
25 able to make rulings on a momentary basis as the need arises,

1 that's what I want to do.

2 I'll let each side react to that. In other words, if we're
3 not going to have testimony in the morning, I want you here at
4 the main courthouse in conference rooms and be across the hall
5 and we're going to get all issues resolved. That's my goal.

6 MR. MONROE: Your Honor, this is James Monroe on behalf of
7 Biogen, and we obviously agree with trying to expedite the
8 resolution of these issues. I would note that if we had -- if
9 we had gone late on Tuesday, just for another hour and a half,
10 as Ms. Bloodworth noted, Dr. Greenberg would have finished all
11 his testimony.

12 THE COURT: I understand your argument. I've taken it
13 into account and I'm moving on and trying to reach a rational
14 decision that will take into account the needs and the wants of
15 both sides. So it's not necessary to repeat that argument. I
16 already heard it.

17 The fact is we didn't finish Dr. Greenberg and we now have
18 to figure out how to do this, and I'm trying to do that. So my
19 question to you -- and it's the only one you need to answer --
20 is are you and your team available to be here in the main
21 courthouse tomorrow morning with Mylan here as well to thrash
22 out these issues so that we can begin the evidence at 1:00,
23 which would be reading in or listening to the deposition
24 testimony of Dr. Lukashev; yes or no?

25 MR. MONROE: Yes.

1 THE COURT: Thank you.

2 MS. BLOODWORTH: Yes, Your Honor.

3 THE COURT: What's Mylan's position?

4 MS. BLOODWORTH: Yes, Your Honor.

5 THE COURT: All right. So I'll have all parties up here
6 at 8:30 tomorrow morning, prepared to go forward and to reach
7 an agreement on how to proceed. To the extent that you cannot
8 reach an agreement, we'll have a hearing in my chambers, get
9 the issues resolved, move on to the next issue, and then we'll
10 resume the evidence at 1:00. Everyone understands that?

11 MS. BLOODWORTH: This is Shannon Bloodworth for Mylan.
12 Yes.

13 MR. MONROE: James Monroe for Biogen. Yes.

14 THE COURT: And Lukashev, I assume, is going to take all
15 afternoon?

16 MS. BLOODWORTH: We have two dep designations that we'd
17 like to play. One is Lukashev. He is -- my understanding,
18 that deposition takes about two hours. And then the second one
19 I think is about be a hour, hour and a half, Your Honor.

20 THE COURT: So then we'd be adjourning probably before
21 5:00 and the next morning would begin with the continuation of
22 Dr. Greenberg's testimony. Is that how I understand it?

23 MS. BLOODWORTH: Yes, Your Honor.

24 THE COURT: And how long would that take? I realize
25 you're thinking through those things, or Mylan is,

1 Ms. Bloodworth, but how long do you expect it to take? Best
2 estimate. Not holding you to it.

3 MS. BLOODWORTH: One and a half to two.

4 THE COURT: Okay. So even with extensive
5 cross-examination, we're likely to be finished early on Friday.
6 Do you have another witness you would be calling after
7 Greenberg, or if Dawson can't be here, then are you going to
8 read or view -- would we view O'Neill's testimony?

9 MS. BLOODWORTH: Yes, Your Honor, we will have additional
10 dep designations after Greenberg, depending upon -- at least
11 one more, and depending on the issue of whether or not the
12 witness would be here live or by dep designations, we would
13 have those designations to play.

14 THE COURT: Do you expect to rest at the conclusion of
15 Friday, or would that be sometime on Monday?

16 MS. BLOODWORTH: It depends on the witnesses'
17 availability, if they're going to be live or not. If we're
18 doing dep designations, it might be Monday morning. Could be
19 by Friday afternoon.

20 THE COURT: All right. Then turning to Biogen's case,
21 once Biogen begins, how long would you expect the case to last
22 on the 112 issues?

23 MR. MONROE: We will be presenting one live witness, Your
24 Honor. That's Dr. Wynn. And his direct should take about two
25 hours.

1 THE COURT: All right. And will there be deposition
2 excerpts put in the record as well, either by video or reading?

3 MR. MONROE: There may be narrow ones that are counters to
4 what they present, Your Honor, if the topics that they're
5 trying to raise by deposition designation are not excluded
6 pursuant to the motion in limine.

7 THE COURT: All right. Then should I expect that this
8 case, including closing arguments, would conclude by Wednesday
9 afternoon?

10 MR. MONROE: Most certainly, Your Honor. Hopefully much
11 sooner than that.

12 THE COURT: All right.

13 MS. BLOODWORTH: Yes, Your Honor.

14 THE COURT: As you know, our court reporter is from the
15 Wheeling point of holding court. She's got scopists who are
16 doing the dailies, and I think it's important that you all keep
17 in mind that she needs to know what the schedule is going to be
18 so that she can form her own judgment about her schedule and
19 also inform her scopists. I would hope that maybe tomorrow or
20 no later than Friday you would be able to give her a pretty
21 good estimate on when the case would conclude in total. Okay?

22 MS. BLOODWORTH: Yes, Your Honor.

23 MR. MONROE: Yes, Your Honor.

24 THE COURT: All right. Thank you. Then we'll see you in
25 here tomorrow morning. And for planning purposes there are --

1 I think your local counsel can advise that there are courtroom
2 conference -- courthouse conference rooms, two that would be
3 available, one for each side. It's not going to take 25
4 persons per side, that's for sure.

5 And the courtroom is going to be used by Judge Kleeh all
6 day tomorrow, so if there's spillage, I think one thing we
7 could do, could do a coin toss and see who would get the jury
8 room, because that's a bigger room and it's not going to be in
9 use tomorrow. And then possibly I could let the other side
10 have the two conference rooms on the second floor, and the jury
11 room is also on the second floor. We might be able to work it
12 out that way so you can bring more of your team.

13 So I suggest bring -- absolutely bring who you need and
14 bring more than who you think you need, if you can limit it to
15 about ten or 12 per side. I think that would work with the
16 space we have available. Okay?

17 MR. MONROE: Thank you, Your Honor. If I could just ask
18 one question for your preferences, Your Honor, we -- as I noted
19 in the beginning, we were intending, because we had not reached
20 some sort of resolution before this call, to file a motion for
21 estoppel if we couldn't agree upon stipulations, so that there
22 would be a record of the estoppel. I think it's clear during
23 this call that Mylan is agreeable to the estoppel, but our
24 clients still like a record of that being in effect.

25 And additionally, we have been intending to file a motion

1 to strike Greenberg's testimony from the first day of the trial
2 about 103 and a motion in limine to exclude with respect to the
3 testimony on the issues that showed up the first time in
4 opening slides. So I didn't want to file those and surprise
5 the Court without raising that issue.

6 THE COURT: Well, you know, based on my read of the
7 statute, a stipulation regarding estoppel is probably
8 unnecessary. And with regard to the striking of
9 Dr. Greenberg's testimony on whether explicitly 103 issues,
10 certainly I, as the fact finder, will not be considering those,
11 since I don't have jurisdiction on those issues any longer.

12 If you want to file things that are -- that your client
13 doesn't understand or decides as a matter of law, feel free,
14 but I just think you should recognize that cluttering up the
15 docket with a lot of unnecessary filings is probably not
16 something we need to get into when we have other issues that
17 really do need to get decided. But you go ahead. You've got a
18 big team. You can do what you want. All right?

19 But if Mylan doesn't agree to your stipulation, I would
20 understand it, given what the statute says. We all understand
21 what's estopped. Based on the SAS case, we certainly
22 understand it. And that's that. All right. If there's
23 nothing further -- go ahead. I'm sorry.

24 MR. MONROE: I was just going to note on that, the
25 striking of the testimony, it really was not about this case.

1 As you're aware, Biogen's patent faces repeat challenges by
2 repeated parties and the concern was the testimony that should
3 not have been elicited in the first place technically.

4 THE COURT: Well, in that regard, that's an issue you have
5 to take up elsewhere. His testimony is on the record here. It
6 was relevant and permissible material at the time it was taken.
7 It's on the record. Now that I understand why you want to
8 strike it, which has nothing to do with this case, forget that.
9 I'm not doing that.

10 MR. MONROE: Okay. Thank you, Your Honor.

11 THE COURT: You're welcome. Take your strategy to the
12 appellate court and see what it says. This Court stands
13 adjourned. Thank you.

14 (Proceedings concluded at 5:05 p.m.)

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1 CERTIFICATE

2 I, Cindy L. Knecht, Registered Professional Reporter and
3 Official Reporter of the United States District Court for the
4 Northern District of West Virginia, do hereby certify that the
5 foregoing is true and correct transcript of the proceedings
6 had in the above-styled action on February 5, 2020, as reported
7 by me in stenotypy.

8 I certify that the transcript fees and format comply with
9 those prescribed by the Court and the Judicial Conference of
10 the United States.

11 Given under my hand this 5th day of February 2020.

12 /s/Cindy L. Knecht

13 _____
14 Cindy L. Knecht, RMR/CRR
15 Official reporter, United States
16 District Court for the Northern
17 District of West Virginia
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